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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,333	09/17/2001	Nigel C. Phillips	028110141US	3284
23370	7590	10/06/2003	EXAMINER	
JOHN S. PRATT, ESQ KILPATRICK STOCKTON, LLP 1100 PEACHTREE STREET SUITE 2800 ATLANTA, GA 30309			ANGELL, JON E	
			ART UNIT	PAPER NUMBER
			1635	
			DATE MAILED: 10/06/2003	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/857,333

Applicant(s)

PHILLIPS ET AL.

Examiner

J. Eric Angell

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,11-14 and 16-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,11,13,22,24 and 26 is/are allowed.
- 6) ☒ Claim(s) 2,12,14,16-21,23,25 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f):
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. This Action is in response to the communication filed on 7/23/03, as Paper No. 14. The amendment has been entered. Claims 1, 2, 11-14 and 16-27 are currently pending in the application and are addressed herein.
2. Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Claim Rejections - 35 USC § 101 and 35 USC § 112

1. Claims 2, 12, 14, 17, 19 and 21 remain rejected, and new claims 23, 25 and 27 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well-established utility for the reasons of record.
2. Additionally, claims 2, 12, 14, 17, 19 and 21 remain rejected, and new claims 23, 25 and 27 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above (and for the reasons of record), one skilled in the art clearly would not know how to use the claimed invention.
3. As indicated in the previous Office Action, claims drawn to methods of preventing inflammation are not supported by either a substantial asserted utility or a well-established utility because the art of record as indicated in the prior Office Action recognizes the complex nature of inflammation, indicative that no single agent will successfully prevent any future occurrence of

Art Unit: 1635

inflammation. Furthermore, as indicated previously, there are no "master drugs" which can prevent inflammation in a mammal, recognized in the art.

Claim Rejections - 35 USC § 112

1. Claims 1, 11, 13, 16, 18 and 20 remain rejected, and new claims 22, 24 and 26 are rejected under 35 U.S.C. 112, first paragraph because the specification, while being enabling for:

A method for reducing inflammation and inducing IL-10 production in an animal having inflammation, wherein said method comprises administering to said animal and effective amount of a composition comprising:

(a) a mycobacterial deoxyribonucleotides acid obtained from a disrupted mycobacterium, wherein said mycobacterium deoxyribonucleic acid is preserved and complexed on a mycobacterial cell wall (BCC); and

(b) a pharmaceutically acceptable carrier, wherein the amount is effective to induce the production of IL-10 and reduce inflammation in said animal.

And also for

A method for reducing inflammation and inducing IL-10 production in an animal having inflammation, wherein said method comprises administering to said animal an effective amount of a composition comprising Mycobacterium phlei-DNA preserved and complexed and a Mycobacterium phlei cell wall (MCC) and a pharmaceutically acceptable carrier, wherein said amount is effective to reduce inflammation and induce IL-10 production in said animal.

Art Unit: 1635

Does not reasonably provide enablement for the full scope encompassed by the pending claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

2. The instant claims are drawn to methods for treating inflammation in a mammal and encompasses methods for treating inflammation in an animal having inflammation and preventing inflammation in said mammal (see claim 16). It is noted that while the preamble of claim 16 indicates that the claim is drawn to a method for treating inflammation in a mammal having inflammation (see claim 16, lines 1-2), lines 4-5 of claim 16 indicates that the amount administered is "effective to prevent the inflammation." Therefore, the claims that are drawn to methods of treatment encompass methods of preventing future inflammation in the treated mammal, as indicated in claim 16. Therefore the instant claims including claim 16 (and its dependent claims) encompass methods of treatment (which does have specific, substantial and credible utility) which encompasses methods of preventing future inflammation (which is not enabled based on the instant disclosure).

3. As indicated in the previous Office Action the claims are very broad and encompass the prevention of any future occurrence of inflammation in a mammal. However, there are no compounds recognized in the prior art which have been proven to completely inhibit all future occurrence of inflammation in a mammal. Furthermore, the Examples provided in the specification do not indicate that the claimed compositions can inhibit any future occurrence of inflammation in a mammal.

Response to Arguments

4. Applicant's arguments filed 7/23/03 have been fully considered but they are not persuasive.

5. Regarding Applicants arguments against the rejection of claims under 35 USC 112, first paragraph for not being fully enabled (see "Preventing vs. treating inflammation"), applicants argue that Examples 3 and 4 of the specification specifically show how mycobacterium can be used to prevent inflammation in mammals. Applicants assert that in Example 3 a solution of carrageenan to induce inflammation was administered to a mammal 2 hours after an initial MCC administration (see p. 6 of the response). Applicants also assert that Example 4 indicates that subcutaneous administration of MCC to the hind footpad 2 hours before carrageenan injection into the same footpad **reduced** inflammation (emphasis added; see p. 7 of the response).

Therefore, applicants contend that examples show how the claims can be used to prevent inflammation.

6. In response, it is respectfully pointed out that Example 3 in the specification appears to be only a prophetic example of how the methods might be used to prevent inflammation.

However, no results of the experiments described in Example 3 are disclosed. Therefore, one of ordinary skill in the art cannot conclude from this disclosure that the method could prevent any future occurrence of inflammation in a mammal. Regarding Example 4, it is respectfully pointed out that although the specification discloses some results for this experiment, the results do not support Applicants contention that the method can be used to "prevent" inflammation in a mammal. The results of Example 4 indicate that an administration of mycobacterial cell wall complex followed by administration of the inflammation –inducing compound carrageenan 2

Art Unit: 1635

hours after administration of the complex did not result in the prevention (i.e. complete inhibition) of inflammation in the mammal, but rather resulted in reduced inflammation 24 hours after carrageenan administration (see page 9, lines 7-11 of the specification). A reduction of inflammation only evident 24 hours after carrageenan administration does not indicate that the mycobacterial cell wall complex can inhibit any future occurrence of inflammation in a mammal. Therefore, considering the unpredictability of preventing any future inflammation in a subject (as set forth in the previous Office Action) and also considering the lack of Examples explicitly indicating that the claimed method can prevent any future occurrence of inflammation, applicants' arguments are not persuasive, and the claims stand rejected.

7. Regarding Applicants arguments pertaining to rejection of claims under 35 USC 101, Applicants contend that claim 2 has been amended to recite certain types of inflammation that can be treated in an animal at risk for those types of inflammation in accordance with this invention.

8. In response, although applicants have amended the claims recite certain types of inflammation that can be treated in an animal; this does not overcome the fact that the instant claims are drawn to method of preventing inflammation in a mammal. Amending the claims to indicate that the methods are for treating inflammation in an animal having inflammation due to the causes set forth in the amended claim (see claims 1 and 2) wherein the administration of the mycobacterial cell wall complex treats inflammation in the mammal (rather than prevents inflammation in the mammal) would obviate this rejection.

Conclusion

9. No claim is allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 1635

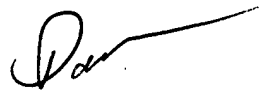
however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is (703) 605-1165. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

J. Eric Angell
Art Unit 1635



DAVE T. NGUYEN
PRIMARY EXAMINER